REMARKS

Rejection under 35 U.S.C. § 102

Independent Claims 1 and 21

The Examiner rejected Claims 1-7, 9-29, and 31-42 under U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,755,797 to Baumgartner ("Baumgartner"). According to the Examiner, Baumgartner discloses "a disc augmentation device for replacement of part of a nucleus (col. 5, lines 49-53) to restore disc height and pressure comprising an annulus augmentation device (Fig 4e) and a spherical nuclear augmentation device (7)."

Applicant respectfully submits that the Examiner has incorrectly characterized Fig 4e as singularly depicting an anulus augmentation device that is distinct from the spherical nuclear augmentation device 7. Applicant asserts that the device shown in 4e is an *integrated construct* comprised of the nucleus augmentation device (i.e. "support member 7") *and* one or more flexible extensions protruding from it. Indeed, Baumgartner explicitly states:

> "As shown in FIG. 4e at least one of the support members, e.g. the last support member 7 to be inserted into the cavity 5 can be provided with at least one and as shown four elastically deformable expansion elements 18, which in the expanded state protrude laterally from the support member 7 and which as represented in FIG.5 are deformed when inserted through the tube 6 in the longitudinal direction into the stressed position 18' and spring back on leaving the tube 6 inside the cavity 5 in the expanded state and thus prevent the support members from leaving the cavity 5 through the through-aperture for the tube." [Col. 5, lines 15-26].

Assuming *arguendo* that Baumgartner's "expansion elements" could be considered an anulus augmentation device, *nowhere* does Baumgartner teach or suggest a anulus augmentation device that is *independent* of the nuclear augmentation device. Baumgartner merely discloses a nuclear augmentation device that is integrated with expansion elements. As amended, Applicant's Claim 1 and Claim 21 recite that "the anulus augmentation device is independent of the nucleus material."

Applicant has also amended Claim 1 and Claim 21 to recite an anulus augmentation device "wherein the anulus augmentation device is configured to resist migration within the disc region bounded by the anulus and vertebral body endplates without depending on the nuclear augmentation material." Assuming *arguendo* that the

device illustrated in 4e in Baumgartner could prevent the nuclear support member from exiting a defect at a given point in time, this device lacks the ability to *remain* in front of the defect where it could continually block other beads or nucleus tissue from extruding. Baumgartner's device is neither anchored in place nor is it adapted to wedge against or within an anatomical structure relative to the defect. In fact, the spherical profile of Baumgartner's device encourages rolling out of the way in response to pressing or compression, as would likely occur in a dynamic disc environment.

Moreover, even assuming the device illustrated in 4e in Baumgartner could "block" the defect at a given point in time, this device could only remain in that position by depending on the nuclear support members. In other words, in the absence of any nuclear support members, the Baumgartner device alone would simply migrate into the disc cavity and cease to augment the anulus. By contrast, Applicant's Claims 1 and 21, as amended, recite that the "anulus augmentation device is configured to resist migration...*without* depending on the nuclear augmentation material."

In light of the amendments and remarks above, Applicant respectfully asserts that Independent Claims 1 and 21 are patentable over Baumgartner. The claims which depend from Claims 1 and 21 are also allowable because they depend from an allowable base claim and further recite independently patentable features.

Independent Claim 23

In accordance with the Examiner's suggestion, Applicant has amended Claim 23 to recite a nucleus augmentation device "wherein said nucleus augmentation material is capable of changing phase within an intervertebral disc space." According to the Examiner, Baumgartner discloses an implant that is incapable of changing phase at body temperature. Thus, in light of Applicant's claim amendment, Applicant respectfully asserts that Independent Claim 23 is patentable over Baumgartner. The claims which depend from Claim 23 are also allowable because they depend from an allowable base claim and further recite independently patentable features.

Objections to Claims

Claim 9 and Claim 31 recite a nuclear augmentation material that is selected from the group consisting of: liquids, gels, solids, and gases. The Examiner appears to object

to claims which depend from Claim 9 and 31 because "if one were to use, i.e. a solid...it would not matter what the gels, liquids or gasses comprise." Accordingly, Applicant has amended Claims 11, 12, 14-17, and 19 and Claims 33, 34, 36-39, and 41 to recite the specific nuclear augmentation material selected. Therefore, Applicant respectfully requests that the Examiner withdraw his objections to these claims.

Rejection under 35 U.S.C. § 103

The Examiner rejected Claims 1, 8, 23, and 30 under U.S.C. § 103(b) as being unpatentable over Bao *et al.* (5,047,055) in view of Bao *et al.* (6,244,630) because "[i]t would have been obvious to one of ordinary skill in the art to combine the teaching of an annulus augmentation device as taught by Bao et al. '630 to a nuclear augmentation as per Bao et al. '055 in order to seal an opening in the annulus that has been initiated surgically and permit natural tissue ingrowth into the annular device."

Applicant respectfully asserts that there is no motivation to combine the '055 patent with the '630 patent. The '630 patent teaches an expanding plug for fixing a hole in the anulus whereas the '055 patent teaches a hydrogel nucleus replacement that expands upon implantation. The '055 patent *teaches away* from the combination of an anulus plug and a nucleus replacement. The '055 patent provides:

> After hydration in the disc, the hydrogel nucleus will be constrained tightly in the cavity from which the nucleus has been excised. The constraining forces are the restoring force of the stretched fibers of the annulus and the external force through the end-plates. The constraint from the annulus and the endplates will restrict the movement of the hydrogel nucleus and prevent it from bulging and herniating from the cavity. [The '055 patent at col. 6 line 47].

The '055 patent explicitly provides that there is no need to "plug" a defect or incision with an anulus augmentation device because the hydrogel nucleus implant has expanded, is larger that the insertion site and that the remaining anulus is more than sufficient to constrain it. Moreover, the '055 patent also discloses that the incision created to allow insertion of the unexpanded (dehydrated) implant will also heal with time: "The incision area on the annulus also can be reduced thereby helping the healing of the anulus and preventing the reherniation of the disc." [The '055 patent at col. 6, line 2]. Thus, when using a nucleus replacement implant according to the '055 patent, the

'055 patent teaches away from combining this implant with an anulus augmentation device.

Moreover, assuming *arguendo* that the expanding anulus plug of the '630 patent was used alongside the expanding hydrogel nucleus of the '055 patent, the resulting combination would be inoperable. As the both the nucleus replacement and anulus plug swell and expand, the plug would likely protrude and impinge an adjacent nerve or be extruded into the spinal canal. This lack of cooperation between the elements would result in an inoperative and physically dangerous combination. Accordingly, in view of the above remarks, Applicant respectfully requests that the Examiner withdraw his rejection of Claims 1, 8, 23, and 30 under U.S.C. § 103(b).

CONCLUSION

In view of the foregoing remarks, Applicant respectfully asserts that the present application is fully in condition for allowance. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number indicated below.

Appropriate fees have been submitted herewith. No further fees are believed to be due. However, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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By: _____

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